IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

HANNAH ELIZABETH COLEMAN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 3:14-cv-01891**
	)	**Judge Frensley**
DEPUY SYNTHES SALES, INC., et a.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

I. Introduction and Background[1]

This matter is before the Court upon a Motion for Summary Judgment filed by the Defendant, DePuy Synthes Sales, Inc. ("Synthes").[2] Docket No. 48. Synthes has also filed a Supporting Memorandum of Law. Docket No. 48-1. The Plaintiff, Hannah Coleman, has filed a Response in Opposition. Docket No. 52. Synthes has filed a Reply. Docket No. 56. For the following reasons, Synthes's Motion for Summary Judgment is GRANTED.

This products liability action arises from the implantation of a piece of titanium mesh manufactured by Synthes into Ms. Coleman's chest in 2012, in an attempt to repair pectus excavatum, a congenital deformity of the anterior chest wall. The surgery was performed by Leonard J. Wudel, M.D., and Robert F. Garza, M.D. In 2014, Ms. Coleman began to experience chest pain, and was seen by Dr. Garza, who ordered a chest CT. On the CT image, an area of

[1] Unless otherwise noted, the facts recited were submitted by the Parties in a form required by Fed. R. Civ. P. 56 and are undisputed.

[2] Synthes contends that "[t]he only proper defendant in this case is DePuy Synthes Sales, Inc., successor to Synthes USA Sales, LLC. The other named defendants have no relationship to this case." Docket No. 48, p. 1, n. 1. Ms. Coleman has not disputed this contention.

mesh had an "accordion" appearance. Dr. Garza agreed with Ms. Coleman that the mesh had become symptomatic and should be removed, and that surgery was performed by Dr. Garza. When Ms. Garza's chest was reopened, Dr. Garza found the mesh to be intact except for a small area at an edge where the mesh had overlapped on itself. After the second surgery, Ms. Coleman felt that her symptoms had mostly resolved.

Ms. Coleman contends that the mesh manufactured by Synthes was defective and caused severe complications which would not have occurred in the absence of negligent or defective design, manufacture, or inspection; and that the mesh was not reasonably suited to the uses intended and reasonably anticipated at the time it left their control. Docket No. 1-1. Ms. Coleman asserts that Synthes is liable under various theories of products liability. *Id.* at 24-27. Synthes denies Ms. Coleman's allegations and has moved for summary judgment on all claims.

II. Law and Analysis

A. Motions for Summary Judgment

Under Fed. R. Civ. P. 56(a), summary judgment is appropriate only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The party bringing the motion has the burden of informing the Court of the basis for its motion and identifying portions of the record that demonstrate the absence of a genuine dispute of material facts. *Rodgers v. Banks*, 344 F.3d 587, 595 (6th Cir. 2003). The moving party may satisfy this burden by presenting affirmative evidence that negates an element of the nonmoving party's claim or by demonstrating an absence of evidence to support the nonmoving party's case. *Id.* A dispute is "genuine" only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505 (1986).

In deciding a motion for summary judgment, the Court must review all the evidence, facts, and inferences in the light most favorable to the nonmoving party. *Matsushita Electric Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348 (1986); *Van Gorder v. Grand Trunk Western Railroad, Inc.*, 509 F.3d 265, 268 (6th Cir. 2007). The Court does not weigh the evidence, judge the credibility of witnesses, or determine the truth of the matter. *Liberty Lobby*, 477 U.S. at 249. The Court determines whether sufficient evidence has been presented to make the issue of fact a proper jury question. *Id.* The mere existence of a scintilla of evidence in support of the nonmoving party's position will be insufficient to allow the nonmoving party's claims to survive summary judgment; rather, the nonmoving party must convince the Court that there is sufficient evidence for a juror to return a verdict in its favor. *Id.*

The Court has reviewed the Parties' Statements of Undisputed Material Facts, as well as the Responses and Reply thereto. Docket Nos. 48-2, 52-1, 52-2, 56-1, 56-2. The Court has determined that there is no genuine dispute as to any material fact. The inquiry thus turns to whether Synthes is entitled to judgment as a matter of law.

B. Rule 7 of the Federal Rules of Civil Procedure

As an initial matter, Ms. Coleman argues that Synthes's Motion must be denied because it fails to comply with "the applicable federal rules of civil procedure," specifically, Rule 7(b). Docket No. 52, p. 5. Rule 7(b), which governs the form of motions and other papers, provides:

> **(1)** ***In General.*** A request for a court order must be made by motion. The motion must:
>
> **(A)** be in writing unless made during a hearing or trial;
>
> **(B)** state with particularity the grounds for seeking the order; and
>
> **(C)** state the relief sought.

> **(2)** ***Form.*** The rules governing captions and other matters of form in pleadings apply to motions and other papers.

Synthes's Motion and Memorandum comply with this rule. *See* Docket Nos. 48, 48-1. Although Ms. Coleman appears to believe that a movant must include all of the grounds and factual bases for its motion in the motion itself, the Court takes judicial notice of the fact that it is common practice to use the supporting memorandum for that purpose, as Synthes has done. *See* Docket No. 48-1.

C. <u>Products Liability</u>

Under the Tennessee Products Liability Act of 1978 ("TPLA"), a products liability action includes all actions based upon the following theories, among others: strict liability in tort; negligence; breach of warranty, express or implied; and misrepresentation, concealment, or nondisclosure, whether negligent or innocent. Tenn. Code Ann. § 29-28-102(6). Regardless of the manner in which a plaintiff characterizes her claims, any claim encompassed by Tenn. Code Ann. § 29-28-102(6) (which includes "any other substantive legal theory in tort") is subsumed by the TPLA. *Id.*; *see, e.g., Strayhorn v. Wyeth Pharms., Inc.*, 882 F. Supp. 2d 1020, 1028-29 (W.D. Tenn. 2012).

Under Tennessee law, an essential element of a product liability claim is that the product itself was in a defective condition or was unreasonably dangerous at the time it left the control of the manufacturer or seller. Tenn. Code Ann. § 29-28-105(a). "The bare fact that a plaintiff is injured is not proof of a defect in the product." *Coffey v. Dowley Mfg.*, 187 F. Supp. 2d 958, 968 (M.D. Tenn. 2002), *citing King v. Danek Med., Inc.*, 37 S.W. 3d 429, 435 (Tenn. App. 2000). "Instead, a plaintiff must prove that the product was defective, regardless of the legal theory upon which he relies." *Id.*, (internal quotation marks and citation omitted).

For the purposes of the TPLA, "defective condition" means "a condition of a product that renders it unsafe for normal or anticipatable handling and consumption." Tenn. Code Ann. § 29-28-102(2). Furthermore, a product is "unreasonably dangerous" if that "product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it . . . or that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller . . . ." Tenn. Code Ann. § 29-28-102(8).

Synthes contends that Ms. Coleman has not established that the mesh was either defective or unreasonably dangerous. Docket No. 48-1, p. 8. Ms. Coleman has pointed to no such evidence, and the Court's independent review of Ms. Coleman's written submissions, including exhibits, has not uncovered any. Ms. Coleman's experts all seem to either have no opinion on the dangerousness or defective nature of the mesh or agree that it is a safe and effective medical device. *See, e.g.*, Docket Nos. 54-3, 48-9 (excerpts from Depo. of Dr. Wudel); Docket Nos. 54-5, 48-10 (excerpts from Depo. of Dr. Garza); Docket Nos. 54-6, 48-12 (excerpts from Depo. of James Wittig, Ph. D., a metallurgist, who opined that the mesh should not have been used in the chest); Docket No. 48-13 (excerpts from Depo. of Kevin Birt, a former Synthes employee).

To establish a products liability claim, proof that the product was defective or unreasonably dangerous is an essential element, and failure to provide that proof is fatal to the claim. *Pride v. BIC Corp.*, 218 F.3d 566, 580 (6th Cir. 2000), *citing Holman v. BIC Corp.*, 925 S.W. 2d 527, 529 (Tenn. 1996); *Tatum v. Cordis Corp.*, 758 F. Supp. 457, 460 (M.D. Tenn. 1991) ("for a plaintiff in Tennessee to recover under ***any theory*** of product liability, the plaintiff must establish that the product was defective or unreasonably dangerous at the time the product left the control of the manufacturer") (emphasis added, internal citation omitted.) For this reason, Ms. Coleman cannot make out even a prima facie case of products liability against

Synthes. This is also true of Ms. Coleman's negligence theory; it is subsumed by the TPLA, and cannot be sustained without a showing that the product was defective or unreasonably dangerous. *Rodriguez v. Stryker Corp.*, No. 2:08-0124, 2011 U.S. Dist. LEXIS 1252 at *35-36 (M.D. Tenn. Jan. 5, 2011) ("the TPLA makes clear that – whatever theory of liability claimed in a products liability action (negligence, warranty, strict liability, etc.) the plaintiff must show injury to person or property resulting from a defective or unreasonably dangerous product"); *Stockton v. Ford Motor Co.*, No. W2016-01175-COA-R3-CV, 2017 WL 2021760 at *3 (Ct. App. Tenn. Feb. 14, 2017) ("whether a plaintiff's claim against a product manufacturer is couched in negligence, strict liability, or breach of warranty, Tennessee courts have held that the plaintiff must establish that the product was defective or unreasonably dangerous at the time the product left the control of the manufacturer"); *Fulton v. Pfizer Hospital Prods. Group, Inc.*, 872 S.W. 2d 908, 911 (Ct. App. Tenn., 1993) ("Plaintiff must prove that the product was defective, regardless of the legal theory upon which he relies").

Ms. Coleman responds that she need not make such a showing, because her claim is based upon a misrepresentation made by a Synthes sales representative regarding the use of the mesh for repair of the chest wall. Docket No. 52, p. 13, 17. If an action is based on express warranty or misrepresentation claims, it is not necessary to prove that the product was defective or unreasonably dangerous. Tenn. Code Ann. § 29-28-105(c). Nevertheless, Ms. Coleman cannot proceed on a misrepresentation claim because she failed to plead it in her Complaint. *See* Docket No. 1-1. Ms. Coleman's Complaint contains no claim of misrepresentation; the Counts are Strict Liability, Negligence, and Breach of Warranty. *Id.* at 24-27. The term "misrepresentation" is found only in one location: when quoting the definition of products liability from Tenn. Code Ann. § 29-28-102(6), with no further elaboration and no factual

support. *Id.* at 25. Even attempting to construe a claim for misrepresentation from the facts in the Complaint, there is no question that such a claim is not pled with particularity.

Similar to claims based on misrepresentation, under Tennessee law, breach of express warranty claims are exempt from the requirement of proving defect or unreasonably dangerous conditions. Tenn. Code Ann. § 29-28-105(a), (c); *Coffey*, 187 F. Supp. 2d at 969. Breach of express warranty encompasses the idea that:

> (1)(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

Tenn. Code Ann. § 47-2-313.

In order to establish a prima facie claim for breach of express warranty, a plaintiff must prove:

> (1) that [the] seller made an affirmation of fact intending to induce the buyer to purchase the goods; (2) that the buyer was in fact induced by the seller's acts; and (3) that the affirmation of fact was false regardless of the seller's knowledge of the falsity or intention to create a warranty.

Coffey, 187 F. Supp. 2d at 969, *citing HBH Enter., Inc. v. Cates*, No. 03A01-CV-00253, 1997 Tenn. App. LEXIS 125 at *2 (Tenn. Ct. App. 1997).

Thus, it is not enough to offer evidence that an affirmation of fact was made; it is essential that the buyer be aware of such affirmation. *See Coffey*, 187 F. Supp. 2d at 973 ("However, it is not clear that [the plaintiff] ever read or specifically relied on these affirmations. For that reason alone, the Court finds that no reasonable jury could find that there has been a breach of express warranty"); *Bearden v. Honeywell Int'l, Inc.*, No. 3:09-1035, 2010 U.S. Dist. LEXIS 83996 at *14 (M.D. Tenn. Aug. 16, 2010) ("Tennessee has adopted the U.C.C., which

provides that an express warranty is created when the seller makes a representation or promise to the buyer that becomes a 'part of the basis of the bargain.' This means that the plaintiff must have been aware of the warranty and must have relied on it when deciding to purchase the product") (internal citations omitted).

It is unclear who, in this instance, the "buyer" truly was. Ms. Coleman appears to contend that it was Dr. Wudel. Docket No. 52, p. 15-17. Synthes contends that "the buyer was the hospital, not Dr. Wudel." Docket No. 56, p. 7. The Court does not have knowledge as to which of these is correct, but the issue is immaterial, as neither Dr. Wudel nor the hospital is the plaintiff in this case, and the actual plaintiff (Ms. Coleman) was not the buyer. Even assuming, as we must, that Synthes employee Jake Washburn made the statements to Dr. Wudel regarding the mesh as Ms. Coleman contends, Ms. Coleman has not put forward any evidence that she relied on any such alleged express warranty. Ms. Coleman has pointed to no authority, and the Court is aware of none, that would allow Ms. Coleman to proceed on a claim of breach of an express warranty from Synthes to a third party.

In her Response, Ms. Coleman discusses the "learned intermediary" doctrine, to illustrate the point that it would clearly be Ms. Coleman's doctor, not Ms. Coleman herself, who would be the person expected to determine whether the mesh was in a defective condition or unreasonably dangerous. Docket No. 52, p. 13-16. Ms. Coleman quotes extensively from *Nye v. Bayer Cropscience, Inc.*, 347 S.W. 3d 686 (Tenn. 2011). That doctrine is inapplicable to the matter of breach of warranty to a third party. Rather:

> The doctrine constitutes a defense by pharmaceutical manufacturers in cases where a plaintiff has suffered injury from a medication prescribed by a doctor. Physicians, who play a pivotal role in the distribution of prescription drugs, are the intermediaries relied on by manufacturers to give warnings to patients. A majority of jurisdictions, including Tennessee,

> recognize that a pharmaceutical manufacturer can discharge its duty to warn by providing the physician with adequate warnings of the drug's risks. In Tennessee, the learned intermediary doctrine is applicable in failure to warn suits where a physician is the intermediary between a defendant pharmaceutical or other medical product manufacturer and an injured patient.

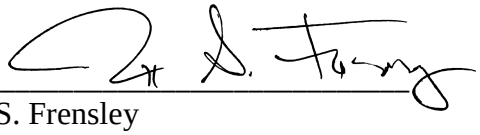
Id. at 701 (internal citations omitted). Thus, the "learned intermediary" doctrine applies to claims for failure to warn, and there is no such claim in Ms. Coleman's Complaint. *See* Docket No. 1-1.

Further, to the extent that Ms. Coleman is claiming a breach of implied warranty, such a claim requires providing evidence that the product was dangerous or defective, something that Ms. Coleman has not done, as discussed above. *See, e.g., Young v. Olympus*, No. 07-2547-STA, 2012 U.S. Dist. LEXIS 9096 at *7-11 (W.D. Tenn. Jan. 26, 2012) (finding that lack of proof that product was defective or unreasonably dangerous was fatal to a breach of implied warranty claim). "A finding that a product was not defective or unreasonably dangerous forecloses an implied warranty claim under the TPLA." *Rodriguez*, 2011 U.S. Dist. LEXIS at *36, *citing Irion v. Sun Lighting, Inc.*, 2004 Tenn. App. LEXIS 210 (Tenn. Ct. App. April 7, 2004). Thus, Synthes is entitled to a judgment on this claim as a matter of law.

III. Conclusion

For the foregoing reasons, Synthes's Motion for Summary Judgment (Docket No. 48) is GRANTED, and this case is DISMISSED.

IT IS SO ORDERED.



Jeffery S. Frensley
United States Magistrate Judge